

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
55-R-0005

CUSTOMER NO.
842

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

NORTH CAROLINA STATE UNIVERSITY
CAMPUS BOX 7514
RALEIGH, NC 27695-7514

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

(b)(2)High, (b)(7)f

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	30	11	182		193
5. Cats	11		148		148
6. Guinea Pigs			20		20
7. Hamsters		93			93
8. Rabbits			338		338
9. Non-Human Primates					
10. Sheep		23	54		77
11. Pigs	174	82	871	1	954
12. Other Farm Animals					
Horses		31	92		123
13. Other Animals					
Llama		1			1
Red Wolves			2		2
Pallas Cats		7			7

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6), (b)(7)c

11/28/2007

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
55-R-0005

CUSTOMER NO.
842

FORM APPROVED
OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

NORTH CAROLINA STATE UNIVERSITY
CAMPUS BOX 7514
RALEIGH, NC 27695-7514

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use this form.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
Cattle		65	37		102
Goats		20	70		90
Horses		31	92		123
Cattle		65	37		102
Goats		20	70		90
Woodchucks			18		18
Gerbils		10			10
Llama		1			1
Red Wolves			2		2
Pallas Cats		7			7
Woodchucks			18		18
Gerbils		10			10

ASSURANCE STATEMENTS

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- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

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11/28/2007

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 55-R-0005

2/3. Species (common name) & Number of animals used in this study:

Pigs (1)

4. Explain the procedure producing pain and/or distress.

Piglets are given an infective dose of *Cryptosporidium parvum* (*C. parvum*) oocysts, an infection for which there are no effective treatments. These infections are typically mild and self-limiting. However, occasionally this infection can lead to varying degrees of dehydration and weight loss secondary to diarrhea and anorexia in some animals. The piglets are monitored closely for appetite, dehydration and other clinical signs and are provided with oral electrolytes if they are not drinking their milk replacer. If piglets do not drink on their own for a period of 48 hours, they are euthanized. Despite close monitoring and administration of oral electrolytes, a few piglets will suddenly become moribund and die before they can be euthanized.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

In order to develop new pharmacologic and/or nutritional therapeutic regimens for *C. parvum* infections, a better understanding of the severity and progression of this disease, from onset to recovery, is needed. No treatments or palliative therapies (other than oral electrolytes) are administered because they are known to influence the disease model. Intestinal motility modifiers, often used to treat diarrhea, result in retention of the organism and increase the extent of infection. Introducing fiber into the diet increases the production of short chain fatty acids that increase intestinal epithelial proliferation and mucus release, thereby modifying the normal results of this model and invalidating the results. The administration of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) inhibits the normal prostaglandin-mediated repair mechanisms and would compromise intestinal epithelial repair that would occur with this model. This condition is not typically painful in people, and analgesics are not typically administered for *C. parvum* related diarrhea in people.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency:

CFR:

North Carolina State University is a land-grant university and a constituent institution of the University of North Carolina

Research and Graduate Studies
Division of Research Administration

(b)(6), (b)(7)c

NC STATE UNIVERSITY

Administrative Services III, Suite 240
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Raleigh, North Carolina 27695-7514

(b)(6), (b)(7)c

November 30, 2007

**ADDENDUM TO THE FY2007 APHIS FORM 7023 SUBMISSION FOR
NORTH CAROLINA STATE UNIVERSITY USDA REGISTRATION # 55-R-0005 / 842**

**EXCEPTIONS TO STANDARDS REPORT FOR THE REPORTING PERIOD OF
OCTOBER 1, 2005 THROUGH SEPTEMBER 30, 2006**

Protocol #1

Species: Dogs

Number affected: 2

Exception to Standards: Fasting dogs for 36 hours prior to an endoscopy training session.

Standard: 9 CFR Ch.1, Pt. 3, Subpt. A, Sec. 3.9 (a) Feeding: Dogs and cats must be fed at least once each day, except as might be required to provide adequate veterinary care.

Justification: A fast of at least 36 hours is required for colonoscopy. The procedure cannot be performed effectively unless the colon is completely empty of solid material. Reference: Jones, BD. Endoscopy of the lower gastrointestinal tract. Vet Clin N Amer: Small Anim Pract 20: 1229-1242, 1990.

Protocol #2

Species: Pigs

Number affected: 6

Exception to Standards: Pigs are housed individually in farrowing crates to prevent potential damage, displacement and/or destruction of intravenous catheters.

Standard: 9 CFR Ch.1, Pt. 3, Subpt. F, Sec. 3.128 Space Requirements: Enclosures shall be constructed and maintained so as to provide sufficient space for each animal to make normal and social postural adjustments with adequate freedom of movement.

Justification: Intravenous catheters are necessary for multiple blood draws over a period of several days, both for the safety of the technicians taking the sample and the comfort of the pigs. If pigs are housed in normal pens while these catheters are in place, there is a very high likelihood that they will roll in urine and feces play in water troughs and/or otherwise contaminate their catheter site or displace or destroy their catheters. In group-housed pigs, there is the additional concern that other pigs will chewed on and displace or destroy the catheters. Placing these 100 kg pigs in farrowing crates designed for larger sows (150 kg), provides sufficient space for them to be comfortable, but will not permit them to roll or engage in other activities that could contaminate, dislodge or damage their catheters.

**ADDENDUM TO THE FY2007 APHIS FORM 7023 SUBMISSION FOR
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**EXCEPTIONS TO STANDARDS REPORT FOR THE REPORTING PERIOD OF
OCTOBER 1, 2005 THROUGH SEPTEMBER 30, 2006**

Protocol #3

Species: Pigs 42

Number affected: Exception to Standards: A group of sows in the Teaching Animal Unit (TAU) are housed in gestation crates to recreate an environment similar to that found on the majority of pig farms in North Carolina. The gestation crates measure 2 ft. wide by 7 ft. 1 in. long, and do not permit the full range of species typical movements or postural adjustments.

Standard: 9 CFR Ch.1, Pt. 3, Subpt. F, Sec. 3.128 Space Requirements: Enclosures shall be constructed and maintained so as to provide sufficient space for each animal to make normal and social postural adjustments with adequate freedom of movement.

Justification: The overall teaching objective and purpose of the TAU are explained in the **Teaching Animal Unit Manual**. "This unit has been designed and is operated to provide veterinary students with live animal laboratory learning experiences with large animals. These units are operated in a manner similar to commercial food animal production units" (page 1 TAU Manual, 2004). One of our goals is to provide students the opportunity to recognize and understand commercial food animal production practices and management, as they would be exposed to in the field as veterinarians. All of our farm animal units are operated as close to commercial standards as possible. The swine unit is a confinement swine operation, farrow to finish. We teach agricultural practices to veterinary students including pig flow, management of the pregnant sow, farrowing, piglet processing, nutrition, ventilation in confinement swine facilities, disease prevention, biosecurity, and pregnancy diagnosis in a natural commercial setting."

Protocol #4

Species: Dogs

Number affected: 9

Exception to Standards: Dogs were maintained in metabolism units that permit most postural adjustments and movements but do not meet the floor space requirements. Smaller dogs were originally requested for the study but were not available. The dogs were housed in these units for periods of up to 48 hours for drug metabolism and pharmacokinetic studies.

Standard: 9 CFR Ch.1, Pt. 3, Subpt. A, Sec. 3.6 (c) (1) (i) and (iii) Primary enclosures -Additional requirements for dogs - Space: Each dog housed in a primary enclosure must be provided a minimum amount of floor space, calculated as described in this portion of the regulations. The interior height must be 6 inches higher than the head of the dog.

Justification: The University Attending Veterinarian and members of the IACUC examined the metabolism units and considered them adequate for the limited period that the dogs will be housed in them. The dogs used for this study ranged from 34-37 inches - nose to tail head length (11.1 to 12.8 sq. ft. floor space required). The metabolism units, after allowing for removal of space for water bowls, provide 10.6 sq. ft. and approximately 2-4 inches above the top of the head (vs. USDA requirements for 6 inches space above the top of the dog's head). Because the dogs were being provided less than the required floor and head space, the investigator agreed to the following accommodations:

- No dog was kept in the metabolism units for more than 48 hours (during sampling portion of the protocol).
- Each dog was removed from the unit at least once each hour during the first 6 hours and allowed to exercise in the room for 5 minutes. Throughout the remaining duration of stay in

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**EXCEPTIONS TO STANDARDS REPORT FOR THE REPORTING PERIOD OF
OCTOBER 1, 2005 THROUGH SEPTEMBER 30, 2006**

- the metabolism units, each dog was exercised on a leash for 5-10 minutes every two hours during the study, with the exception of the night-time hours when the lights are turned off in the room.
- Unit hygiene was maintained by cleaning as frequently as necessary whenever soiling of the cage was observed.
- Dogs received an approved diet and continual access to water while in the metabolism units.
- The Principal Investigator or his colleague, both licensed veterinarians, inspected each dog throughout the stay in metabolism units for any clinical signs or lesions associated with this period of confinement.

Any questions or comments regarding these exception reports may be directed to the University Attending Veterinarian who prepared this report.

Respectfully submitted,

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North Carolina State University
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Raleigh, NC 27695-7514

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APHIS Form 7023 Additional Reported Sites

The following additional sites have been reported by the facility. The reported sites have not been verified by APHIS and have been provided by the facility solely for completeness of the APHIS Form 7023 Annual Reporting submission.

Registration Number: 55-R-0005
Customer Number: 842
Facility: NORTH CAROLINA STATE UNIVERSITY
CAMPUS BOX 7514
RALEIGH, NC 27695-7514

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